REMARKS/ARGUMENTS

Claims 1-10 and 12-16 were pending. Claims 1, 2, 9, 10 and 14-16 are hereby amended, claims 3 and 4 are hereby canceled and new claims 17 and 18 are hereby added. Therefore, upon entry of this amendment, which is respectfully requested, claims 1, 2, 5-11 and 12-18 will be pending.

Claims 1-10 and 12-16 were previously rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. Applicants respectfully traverse this rejection.

Amendments to these claims were made, *inter alia*, to recite comparing a test data set and the reference data sets by applying a k-nearest neighbor (KNN) process. It is respectfully submitted that the present specification adequately describes the application of a KNN process or algorithm to a test data set and reference data sets in a manner that enables one skilled in the art to practice the invention. In particular, the specification teaches and guides one skilled in the art how to implement a KNN process in the context of multianalyte test sets, including multiple refinements, to produce a statistically derived decision useful for indicating or diagnosing which disease(s) a patient's test data set may be associated with. See, *e.g.*, page 5, line 14 to page 6, line 2. For example, the specification teaches that the reference data sets may be determined from multianalyte analyses and entered into a database. Each data set is effectively an N-dimensional vector identifying a point in an N-dimensional space, wherein the coordinates of each point represent the values of the test results, one coordinate for each of N tests. See, *e.g.*, page 4, lines 16 to 29. Similarly, the test data set is determined from multianalyte analysis, the test values of which represent coordinates of a test point in the N-dimensional space. Using a KNN process, the K reference data points having the closest distance to the test data point in the N-dimensional space are determined, and the one or more diseases associated with the K closest points may be used for diagnosing the patient.

The specification teaches how to process a test set with respect to reference data sets using a KNN process, and how to create reference data sets with sufficient specificity to allow one skilled in the art to implement the invention. It was alleged that the specification does

not exemplify or identify any known library of reference data sets, however, it is not necessary that "libraries" of reference data sets currently exist. The specification teaches how to create such reference data sets with sufficient specificity to enable one skilled in the art to create a useful library of reference sets of any size. Again, reference data sets are created using the values of multianalyte tests on a biological sample of a reference subject known to have a disease of known identity. The data values may be input into a database or otherwise stored as is well known. It may be desirable to normalize the values for the multianalyte tests, or otherwise modify input values to provide a refined process, however, such data manipulation is well understood and is readily within the ability of one skilled in the art. The present invention teaches the various aspects necessary for one skilled in the art to implement a computer-implemented method as recited in the present claims.

It was also stated in the prior rejection that although claim 5 encompasses a test data set of up to 100 autoantibodies, the specification specifically identifies less than half of that number. It is respectfully submitted that the specification specifically identifies a number of autoantibodies and also references an article by J.B. Peter at page 7, line 6 for additional autoantibodies that are known to be expressed in autoimmune diseases. It is also known that more than 100 autoantibodies are known to be expressed in autoimmune diseases. Therefore, to the extent the specification and the J.B. Peter reference do not specifically identify up to 100 autoantibodies, it would be a routine matter for one skilled in the art to research sources to identify additional autoantibodies.

Accordingly, it is a routine matter for one skilled in the to implement such computer-implemented methods as recited in claims 1 and 18, and all dependent claims, based on the description given in the specification without undue experimentation.

Claims 1-10 and 12-16 were also previously rejected under 35 U.S.C. §112, second paragraph, as being indefinite. It is respectfully asserted that the amendments made to the claims herein render this rejection moot.

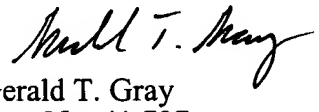
It is respectfully submitted that no new matter has been added by the amendments made and the new claims added.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is urged.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 925-472-5000.

Respectfully submitted,



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